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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/593,425	12/27/2006	Jorg Feesche	H06291 (13744-00021)	5960	
2341.6 7550 04/17/2009 CONNOLLY BOVE LODGE & HUTZ, LLP			EXAM	EXAMINER	
P O BOX 2207			PORTNER, VIRGINIA ALLEN		
WILMINGTON, DE 19899			ART UNIT	PAPER NUMBER	
			1645		
			MAIL DATE	DELIVERY MODE	
			04/17/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/593 425 FEESCHE ET AL. Office Action Summary Examiner Art Unit GINNY PORTNER 1645 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 8/12/2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4)\ Claim(s) 1.2.5-11.13.14.16-21.23-33 and 48-54 is/are pending in the application. 4a) Of the above claim(s) 34 and 54 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected 7) Claim(s) is/are objected to. 8) Claim(s) 1,2,5-11,13,14,16-21,23-33 and 48-53 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date \_

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

Other: See Continuation Sheet.

5) Notice of Informal Patent Application

Continuation of Attachment(s) 6). Other: sequence letter, Notice to comply.

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#### DETAILED ACTION

Claims 1-2, 5-11, 13-14, 16-21, 23-34, 48-54 are pending.

Claims 34 and 54 are improper multiple dependent claims because the claims depend from two claims simultaneously, rather than in the alternative,

## Claim Objections

1. Claims 34 and 54 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from prior claims in the alternative and not simultaneously. See MPEP § 608.01(n). Accordingly, the claims 34 and 54 will not been further treated on the merits. Upon claim amendment to present the claims in proper format, the claims will be placed in a new group or a group set forth below in the Lack of Unity.

#### Lack of Unity of Invention

Please Note: In light of US-PG-Pub 2008/005077, which has an effective filing date under 35

USC 102(e) of January 9, 2004, and disclosing the first appearing invention (see sequence

alignment provided below), a Lack of Unity of invention is being set forth

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PG-Pub 2008/0050774's SEQ ID No 1 and 1819 share 99.5 sequence identity at the nucleic acid level with instantly claimed SEQ Id NO 1; priority document 60/535,988 (filing date January 9,2004).

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, drawn to a protein RecA from Bacillus licheniformis.

Group II, claim(s) 5-7 and 31-32, drawn to a nucleic acid encoding a factor RecA of SEQ ID NO 1, or encodes the amino acid sequence SEQ ID NO 2.

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Group III. claim(s) 8-10, 11, 13-14, 16 and 48, drawn to a plurality of methods of functionally inactivating the gene recap in a gram positive bacterium.

Group IV, claim(s) 17-1, 23-28, drawn to a gram positive bacterium with an inactivated recA gene, and a method of fermenting the bacterium.

Group V, claim(s) 26-28, drawn to a plurality of methods of making a low molecular weight compound, a protein, an enzyme, a natural product, a nutritional supplement or a pharmaccutically relevant compound.

Group VI, claim(s) 29-30, drawn to a method of improving a molecular biological reaction.

Group VII, claim(s) 33, drawn to a method of manufacturing factor RecA (no methods steps recited).

Group VIII, claim(s) 49, drawn to a method of inactivating a factor recA gene with anti-sense DNA.

Group IX, claim(s) 50-53, drawn to a plurality of methods of amplifying DNA utilizing a combination of two nucleic acids.

- 2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The first appearing invention does not define a special technical feature that makes a contribution over the prior art in light of US PG-Pub 2008/0050774, with the effective filing date of January 9, 2004, which describes the claimed special technical feature. The claimed inventions lack unity of invention in light of the description and disclosure of US PG-Pub 2008/0050774.
- 3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group III claims a plurality methods of making a plurality of species of gram positive bacterium with an inactivated recA gene, each species differing in structure, function and biological effect, as each species has a different gene inactivated:

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(species 1-14, claim 8 or 14) recA inactivation or a combination of recA inactivation together with spoIVA, spoIVB, spoIVCA, spoIVCB, spoIVFA, spoIVFB, yqfD, homologs of the listed genes, or

(species 15-95 claim 16) recA inactivated together with the combination of spoIVA, spoIVB, spoIVCA, spoIVCB, spoIVFA, spoIVFB, yqfD, spoIVor homologs of the listed genes and additionally together with SEQ ID NO 3, 5, 7, 9, 11, 13, 15, 17 or parts thereof.

Group IV claims a plurality of species

(species 1-14, claim 17 or 21) recA inactivation or a combination of recA inactivation together with spoIVA, spoIVB, spoIVCA, spoIVCB, spoIVFA, spoIVFB, yqfD, homologs of the listed genes, or

(species 15-95 claim 23) recA inactivated together with the combination of spoIVA, spoIVB, spoIVCA, spoIVCB, spoIVFA, spoIVFB, yqfD, spoIVor homologs of the listed genes and additionally together with SEQ ID NO 3, 5, 7, 9, 11, 13, 15, 17 or parts thereof.

## Group V: method makes species:

- low molecular weight compound (claim 26)
- a protein( claim 26)
- a natural product (claim 27)
- 4. a nutritional supplement (claim 27)
- 5. a pharmaceutical (claim 27)
- an enzyme (claim 28)

Group IX methods of amplifying with two nucleic acids: (claims 50-52 and 53)

a. (species 1-5) SEO ID NO 25 with SEO 26, or 27 or 28 or 29 or 30

b. (species 6-9) SEQ ID NO 26 with SEQ 27 or 28 or 29 or 30.

c. (species 10- 12) SEQ ID NO 27 with SEQ 28 or 29 or 30.

d. (species 13-14) SEQ ID NO 28 with SEQ 29 or 30.

e. (species 15) SEQ ID NO 29 with SEQ ID No 30.

f. (species 16) the bacterium has both sporulation and recA genes inactivated, and

used in combination with one of the species (1-15) listed immediately above (claim 53)

Applicant is required, in reply to this action, to elect a single species to which the claims

shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive

unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of

claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP

§ 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner

Group III: Claims 8 or 14 or 16 recite a plurality of species.

Group IV: Claims 17 or 21 or 23 recite a plurality of species.

Group V: claims 26-28 recite a plurality of species.

Group IX: claims 50-53 recite a plurality of species.

The following claim(s) are generic: no claims are generic.

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5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species of invention differs structurally, and functionally from the other species because each species has a different gene (claim 21) or genes (claim 23) inactivated by point mutagenesis, partial deletion, insertion or total deletion (claim 18); the differing gene structure results in different biological effects.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

- 7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

# SEQUENCE COMPLIANCE

9. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth below. Failure to fully comply with both these requirements in the time period set forth in this office action will be held non-responsive.

10. Examiner would like to point out that there is no information with regards to SEQ ID NO: of the sequences present in Figure 1 and 2, in the Brief Description of the Drawings for the mentioned Figure 1 and 2. If the Drawings contain amino acid sequences that are encompassed

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by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a((1) and (a)(2) then the Brief Description of the Drawings needs to state the SEQ ID NO: for the nucleotide and/or amino acid sequences. Unless the appropriate SEQ ID NO: accompanies the nucleotide and/or amino acid sequences in the actual Drawing sheet.

#### General Observations

### Specification

- 11. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. (see paragraphs 12, 29, 30, 65, 147).
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/ Examiner, Art Unit 1645 April 13, 2009

/Robert B Mondesi/ Supervisory Patent Examiner, Art Unit 1645